Role of Scientific Data in Health Decisions

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The distinction between reality and models or methodological assumptions is necessary for an understanding of the use of data — economic, technical or biological — in decision-making. The traditional modes of analysis used in decisions are discussed historically and analytically. Utilitarian-based concepts such as cost-benefit analysis and cannibalistic concepts such as "acceptable risk" are rejected on logical and moral grounds. Historical reality suggests the concept of socially necessary risk determined through the dialectic process in democracy.

The dependence of those who make decisions in the fields of public, environmental and occupational health on concepts borrowed from other sciences and applied with poorly contrived modifications results in unnecessary barriers to the development of methods appropriate to a health science.

The consequence is that when the call comes for decisions made on some kind of rational basis, the health practitioner finds himself in the position of the hound who must lean against the wall in order to bark.

In the recent decision on OSHA's benzene standard (1), the Court of Appeals was convinced that the agency ought to quantify what cannot be quantified (the health benefits) and to compare these values with incommensurable values derived from economic data. The intellectual errors are not those of the court alone. Those of us who participated in the hearings conducted by the agency — labor, management, public interest organizations and government — failed to construct an alternative mode of analysis.

In the recent estimate of the fraction of cancer attributable to occupation (2), the contributors point to the importance of a methodological error which can result in a gross underestimation (1-5%) of the occupationally-related fraction. When "the fallacy of one effect — one cause" explanations" is recognized and correctly replaced by the concept of multiple "factors," the value at issue becomes "at least 20%."

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The frequently unheuristic use of "models," explanatory concepts, working hypotheses, systematizing statements and other methodological conveniences stems in great part from the recurrent arrogance that considers philosophic analysis as something distinct from and unrelated to what is called "science." Yet, because explanation is impossible in terms of "science" alone, we either construct or unconsciously assume a crude metaphysic, or accept uncritically handed down systems.

The fault of scientists and their educators? The fault of an introvertish period of philosophic inquiry? Regardless of fault, we are in the difficulty of finding that what so many call word-quibbling or consider to be "just semantics" should be so vital to the progress of our science. Yet we are not prepared to deal with these philosophic issues.

The lack of unity and clarity of principles and the cobweb of terminological inconsistencies in the field of health decision-making prevent us from developing a systematized body of propositions or at least understandings, i.e., a specialized science.

A specialized science with this charge draws its data from perceptions of our mores, our politics, the laboratory, the field, the clinic and our personal and social values. Decisions are being made and these data are being collected, but the distinct threads we perceive form no rational pattern, only a knot.

Part of the problem is that we train many specialized scientists, but few general scientists. The consequence is that we have difficulty in progressing beyond what Whitehead (3) would have called a "medley of ad hoc hypotheses," because philosophic criticism seldom occurs diligently and with discipline.

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Each of the specialties feeding data to the decision-makers explains their conclusions in terms of a system of assumptions formed in their science. The explanations often lose meaning because the meaning is understood by going outside that system. The conceptual doors to alternative explanations are closed because the assumption "works" for the purpose of that one science.

It is elementary, but important to reiterate that every science makes assumptions in advance of certainty. These are methodological assumptions which even if proven to be heuristic for the purpose of an investigation are not necessarily "true" for the purpose of other investigations and, if they are, not necessarily true of all reality.

We do not question the truth of a mathematical entity, provided that it is self-consistent. But we must continually question the veracity of a system into which we place empirical constants, or interpret the signs and symbols, e.g. give them conventional meaning. We question by constant reference to experience.

Woodger (4) clearly propounds such an approach for biology from which we can learn:

"It is without sense to ask whether the axioms in an uninterpreted system are true, and all that is meant by saying that the theorems are true is that they are derivable from the axioms in accordance with the rules of inference adopted, i.e. rules for transforming one sentence in the system into another. Such a system becomes of interest to natural science if, on substituting empirical constants for its variable, we obtain significant sentences that are not contradicted by observation."

Even from the theoretical standpoint, the practical activity is the only ultimate source of statement validation. With respect to the system per se, the analytical role of the rules is the source of validation; but if such statements or their consequences can not be empirically confirmed, then both the rules and axioms may be changed to "fit" the system to use. This confers upon the scientist order to his records, direction to his activities, and an analytic tool useful in expanding the data base and our conceptual horizons.

Some statements in such a system can not be verified, but find justification for their continued use to be their systematizing value. They become methodological contrivances. The meaning of such devices is confined to their systematizing function. This is not always recognized by the practical worker, who finds it necessary to make an imaginary extension of such unverifiable entities to reality.

Gehring (5) uses barrels with triangular slits, for example, to provide "a conceptual basis" . . . "for

why metabolic thresholds may lead to a disproportionate increase in toxicity. . . ." This kind of extension should not lead to controversy about the reality and characteristics of such entities, yet their use in OSHA hearings to justify the continued use of the 'TLV' concept (6) in the control of workplace carcinogens has had precisely this result.

In economics, a similar extension of the imagination takes place when the concept or model of the free marketplace is assumed or used.

Knight (7) lists the characteristics of such a system: freely contracting individuals, perfectly rational behavior, perfect mobility, complete knowledge of exchange possibilities and technical significance, ideal wants, free access to market, purely individual desires, free banking and currency, individual provision for the future, a rational attitude toward risk and chance, and perfect distribution of rewards according to productive contribution. This concept can not survive the test of real life.

Do such extensions take place just to systemize? A parable by Kafka (8) is brought to mind by this question: "Since the Fall we have been essentially equal in our capacity to recognize good and evil," he begins. He goes on to say: "... nobody can remain content with the mere knowledge of good and evil in itself, but must endeavour to act in accordance with it." In this attempt, he concludes, "man is filled with fear; he prefers to annul his knowledge ... yet the accomplished cannot be annulled, but only confused. It was for this purpose that our rationalizations were created. The whole world is full of them, indeed the whole visible world is perhaps nothing more than the rationalization of a man who wants to find peace of a moment."

Most communication is the process of transmitting not knowledge, but rationalization or the imaginary extension to reality.

If such communication is rejected by the proposed receptor, not simply the message but even the medium, then the perception—polarized by reality—is protective. In the case of the issue of the environment of workplace or community, what is being protected may be life itself.

Rationalizations take different forms. They may be simply construed imaginary extensions, or they may be complex constructions from carefully selected data. In occupational health decisions, the only protection the worker has against either form is his own reality, the reality he is able to perceive.

Here an important distinction must be made between various frames of discourse, because what is "right" and "wrong" (in this context) is relative to its discursive frame. Some frames are axiomatic systems or subsystems. Others are without sufficient consistency to be called systems. They are simply rough areas of discussion.

This is a difficult concept to grasp, so concreteness may be helpful. If, for example, the issues in the discourse involve simply construed extensions of our imagination (the existence of safety or thresholds for populations) or complex constructions (such as the concept of "acceptable risk," the use of "riskbenefit analysis" when dealing with incommensurables, or the alleged prevalence of the demand for a "zero risk environment"), then the discourse can go forward but only by making believe, by playing a game in which we speak as if our statements are verifiable.

To avoid semilogical fallacies (which occur when the same term in the same context is given more than one meaning) we learn to accommodate our meanings in any dialogue so that the denotation (including the qualifications) of the term, for the purpose of dialogue, becomes the same or similar in meaning for each actor. For at least one participant in the dialogue (usually all) the meaning of the concept actually changes. So we continuously hear implied or explicated redefinitions of "risk-benefit analysis," a process which is essential to communication. Within the frame of that dialogue, when the adjustment has been made, the acceptance and use of the concept is "right," i.e., an heuristic methodological assumption has been made by at least one actor, an assumption that need not "fit".

The difficulty is that when the concept is discussed in the broader, public frame of discourse a denotive-connotative fallacy may occur. That is to say, the denotative meanings — private redefinitions — conflict with the broader, public connotative meaning given the terms by observers of the dialogue who have not or can not be cognizant of the methodological use or redefinition. Within that frame, the acceptance and use of the concept is "wrong" because it is known by the actors to be extended beyond the meaning of the term as a systematizer for the sake of discussion.

Since dialogue or communication becomes less effective as the number of people involved increases, we must reject the use of terms that require massive re-education for its redefinition. The solution is simply to find another term.

In the recent OSHA cancer policy hearings, I questioned Upton (NCI), Rall (NIEHS), and Schneiderman (NCI) on what each meant by risk-benefit analysis (a term they each used). Confronted with the conventional meanings, they essentially agreed with Rall that another term would be more useful in conveying their position on the social, decision-making process of carcinogen regulation.

Perpetuating the conventional meaning of

"cause" in discursive frames where "factor" would be more appropriate is another example. The conventional meaning of "cause" is essentially Newtonian: stressing the agentive and material sides of Act and Effect. The concept favors the explanation of the action of single agents or mechanisms in isolation; it has difficulty in accounting for statistical, multi-variate factor analysis. Yet, as we know, these concepts are both heuristic within an appropriate frame of discourse. The study of pharmaco-kinetic pathways fruitfully have assumed Newtonian cause and effect relationships. Population studies (e.g. risk assessments) fruitfully have assumed chance relationships.

There has not yet been a broad realization that the concepts of safety, thresholds of "no effects" in populations, one-cause and one-effect are often not heuristic. Our failure to find heuristic alternative tools means the perpetuation of overly simplistic regulatory concepts which we cannot abandon because we have no replacement. What is widely suggested for filling the void really fills the pots of the latter-day cannibal: the concept of acceptable risk.

The connotation of the term "acceptable risk" is intellectually and emotionally appealing. When a taskforce (9) of respected government scientists, having failed to find either the empirical or theoretical bases for "thresholds," suggested to regulators a socioeconomic solution for determining the allowable extent of carcinogenic exposure, they suggested the method of "socially acceptable risk."

At that time the concept had very little meaning because there was little effort to develop a methodology for the determination of such risks. Subsequent work has provided us with a profuse literature, of which this paper is a part. Based on the recent denotation, the term has lost its appeal.

Those who espouse the prevalent concept of acceptable risk generally assume a number of fallacies, including: (1) that the persistence of a risk is evidence that it has been accepted by those at risk, (apathy, ignorance and lack of choice notwithstanding), and (2) the process of deciding whether or not a risk will be taken is on the basis of cost-benefit analysis, an analog of the primitive utilitatianism: "the greatest good for the greatest number." In this process the worker fares poorly; he is selected for unnecessary and unwarranted risks; he is cannibalized.

Lowrance (10), whose work appears to be quoted most frequently, depends substantively on an assessment of attitudes among those at risk: "Our attitudes about risks and our assignment of responsibility for minimizing them still seem to be imbalanced by whether they are encountered on or off the job."

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Part of the problem of an attitudinal approach is what the perceptor believes to be "the facts" (10). If by safety we mean no observed adverse effects, a "threshold" would mean a level of dose below which there is no such effect. The case has often been made that no threshold has been found for chemical or radiation carcinogenesis or mutagenesis. Lowrance makes the case, with Stokinger (6), inconsistent with the uniformity of nature, that thresholds "clearly" exist for noncarcinogenic risks. Others dispute this "fact."

Rall (11), observing the effects of sulfur oxides, believes that "the concept of no-effect level may be a chimera." An isolated opinion? A committee of the National Academy of Science concludes, in assessing the risk of toxic chemicals, that "(the term 'no-effect level') is statistically meaningless . . ." (12).

What happens, for the purpose of dialogue, when we redefine "safety" to mean "risks . . . judged to be acceptable." (10) is that, aside from the risk of a denotative-connative fallacy, the attitude of separating risks "on" or "off" the job becomes a critical consideration.

To quote Lowrance (10), "It has traditionally been accepted that pursuing one's trade will almost inevitably bring a peculiar set of risks, and further, that such risks may allowably be greater than for non-occupational activities. This attitude has strong historical momentum."

The "momentum" is a fact, the attitude that it is "generally agreed" that most industrial accidents (and even a large number of illnesses) are precipitated by "ignorance, absent mindedness, negligence and foolhardiness" (10) may not be a fact. The president of the American Society for Safety Engineers (13), for instance, takes issue with Lowrance: "Instead... it is generally agreed that most accidents are associated with multiple causal factors, some relating to the actions of people."

Aside from the question of the pseudo-historic acceptability of occupational risks, even the assumption of such acceptability in the past is not a premise in its acceptability in the future. It is a premise for the creation of a class of expendables allowably selected for sacrifice by society.

Part of the rationale for the sacrifice is an attempt to give credence to the myth of risk willingness, demonstrated by comparing unregulated risks through loose analogy with incommensurable situations proposed for regulation. Pochin (14) compares sports spectacles with nuclear risk with occupational risk. Part of the rationale is found at the very base of the truly historic dialogue on the regulation of human behavior: the blind acceptance of the greatest good for the greatest number.

The greatest good (determined by special interests

in a position to have social leverage) for the greatest number (without regard for the welfare of the less powerful few) means precisely that form of collective tyranny which we as a society supposedly reject. It is a game in which the rules can be changed at the will of the most lawless players regardless of the toll in human life or the distortion of the humblest concept of truth.

Ironically, it can result in precisely those despotisms most feared by the well-meaning utilitarian progenitors of some of the concepts abused in this game.

The key concept was expressed in the context of the Industrial Revolution and the concurrent surge toward confusing quantification with science by the primitive utilitarian Jeremy Bentham (15).

"Take an account of the *number* of persons . . . concerned . . . *sum up* the numbers expressive . . . of good tendency . . . with respect to each individual . . .; do this again with respect to (the) bad. Take the *balance*; which, if on the side of pleasure, will give the general *good tendency* of the act, with respect to the total number or community of individuals concerned; if on the side of pain, the general evil tendency, with respect to the same community."

His "felicific" calculus, reducing collective good and bad to quantified common values of pleasure and pain, the ancestor of cost-benefit analysis, was later qualified by Mill (16).

"The great majority of good actions are intended not for the benefit of the world, but for that of individuals . . . the thoughts of the most virtuous man need not . . . travel beyond the particular persons concerned, except so far as is necessary to assure himself that in benefitting them he is not violating the rights, that is, the legitimate and authorized expectations, of anyone else."

Cost-benefit analysis, as defined by Rowe, (17), is "an attempt to delineate and compare in terms of society as a whole the significant effects, both positive and negative, of a specific action. Generally a number of alternative actions are analyzed, resulting in the selection of the alternative that provides either the largest benefit-cost ratio (total benefit/to total cost) or one with a positive ratio at least. . . ."

Epstein (18) uses the concepts of "efficacy" and "social utility" in matching benefits against hazards for the purpose of simplifying "the benefit hazard equation."

The definition thus far is Bentham's felicific calculus. The Mill qualification appears in Rowe as "inequities reasonably ameliorated" (17). The same qualification appears in Mishan's (19) cogent definition: "The rational of existing cost-benefit criteria is ultimately that of a potential pareto improvement." By pareto improvement he means a change in economic organization that makes one or more members of society better off without making anyone worse off.

Neither Rowe nor Epstein nor Mishan see cost-

benefit analysis as a tool for cannibalizing one segment of our population for the sake of another. The problem is how to determine the "inequities" or calculate the "worse off."

Rowe suggests a number of approaches to the problem of equity, including the work of physicist Richard Wilson.

In Wilson's testimony at the OSHA hearings on carcinogen policy (20), on behalf of the American Industrial Health Council, a chemical industry group, he said that the pareto consideration was too complicated. His direct testimony provides us with this simpler concept: "... are the benefits properly disaggregated... do enough... accrue to those directly undertaking the risks? This can, in an extreme case be by compensation of hazard pay."

Hazard pay — in a society that historically prides itself in a less than full employment economy and where risks are seldom undertaken voluntarily — is the conventional expression of cannibalism in America.

Testifying at the same hearing for the American Petroleum Institute, economist Richard Zeckhauser took a diffferent position (21).

"... the agency argues (that) cost-benefit analysis (is) inappropriate. We would agree that health is not a traditional commodity and that there are no widely accepted techniques for assigning dollar values to health outcomes... We are not arguing that a cost-benefit approach be employed in formulating policy on occupational safety and health." Professor Zeckhauser argued for a defensible cost-effectiveness approach.

Even if one were to assume that an individual really has a choice, shifting the question from cannibalism to suicide, problems remain.

Mishan notes (19) that "in determining whether a potential pareto improvement has been met, economists are generally agreed—either as a canon of faith, as a political tenet, or as an act of expediency—to accept the dictum that each person knows his own interest best."

Aside from the question of whether such knowledge is possible, given the reality that each man has imperfect knowledge, Mishan makes the historic assumption about economic man, stated very early by Edgeworth (22): "The first principle of Economics is that every agent is actuated only by self-interest."

In other words, cost benefit analysis assumes that altruism either does not exist or is an unimportant factor. It assumes that the agent knows his self-interest and acts rationally in accordance with this knowledge. These assumptions are unheuristic. They are not warrantable in either the best or (depending on your Weltanschauung) the worst of all possible worlds. These are not the only assumptions

of an unheuristic nature made in cost or risk-benefit analysis.

In cost or risk-benefit analysis, we have displayed before us a system of forced quantification which often leads to what Georgescu-Roegen (23) calls the Arithmomorphic Model or what I call the Arithcentric Fallacy: numbers = precision, precision = truth, ergo numbers = truth.

More than half a century ago Viner (24) warned his fellow economists against the "all too prevalent methodological fanaticism which prefers the accurate but superficial to the approximate but fundamental, and which makes adaptability to its special technique of investigation, rather than importance, the standard for the selection of problems and the delineation of the scope of its inquiry."

Despite these warnings, the arithcentric fallacy is frequently displayed in ignoring the necessity of commensurable values in a calculus. Thus we find risk-benefit proponents (25) comparing the risks of saccharin with cigarette smoking with street crossing with automobile riding with the risk of cervical cancer among women who do not have an annual test—all for the sake of quantification for the sake of risk-benefit analysis presumably for the sake of finding the elusive "acceptable risk."

Wilson correctly compares (20) the risks of x-ray and the benefits (averting another risk) of disease diagnosis because the same person is involved and the risks and benefits have a common value: longevity of that one individual.

But for the sake of quantification he equates assessments that have no common values. He extrapolates without qualification data from animal studies (20) for the quantification of human risk. He makes the same error in extrapolating and comparing data from epidemiologic studies (20), confusing the risk of asbestos-exposed smokers and asbestosexposed nonsmokers. In the case he uses, the ratio of observed to expected has as its denominator white male death rates of smokers and nonsmokers taken from the national rate. Thus for lung cancer among asbestos-exposed noncigarette smokers the ratio is 2/1.58 (20). In testimony before the same hearing, Selikoff introduced another study in which the denominator is (a) matched to the asbestos worker cohort and (b) compares nonsmokers to nonsmokers. Understandably, the ratio derived is different: 4-5/1. Which one describes the risk? The risk of asbestos exposure for the individual is indeterminate if it is not relative because it is absolute. The calculation of absolute values is not possible. The comparison of ratios whose denominators have no common value is not possible.

Nevertheless, from this exercise in quantification Wilson derives an "acceptable" numerical level or

threshold (20) of historically persistent risk. His "table" (20) compares questionable "accident" rates with mixed questionable "accident" and disease rates and labels them all "Current Occupational Risks." He calculates from this nonsense a threshold "yearly risk less than 10^{-5} / year as one in which the reduction can be left to industry but that OSHA action would almost inevitably cost more than is justified" (20).

Even if the methodological errors of Wilson are corrected, the problems of subjectivism in a statistical calculus for decision-making remain. Tversky and Kahneman (26) make the point that internal consistency is not the only criterion to evaluate judged probabilities. "The judgments must be compatible with the entire web of beliefs held by the individual."

The failure in economic judgments to follow Viner's advice is found less among economists than it is among others who use the arithcentric technique without understanding. A committee of the National Academy of Sciences (27) taking the advice of its economist-members, concluded: "We have found traditional benefit-cost analysis to be not very useful in making decisions about regulating chemicals. The most important and pervasive limitation on benefit-cost analysis is the role of values. Many of the factors that are likely to be most significant in a decision concerning toxic chemicals cannot be measured in common terms (such as dollars) that are agreeable to all concerned parties. . . ."

These are not arguments against increasing the precision with which we make biological risk or economic (or even social) benefit assessments in order to achieve a balance of judgment. What is being questioned is how and in what form the data can be developed and used. We cannot ignore values simply because we cannot quantify them, or distort them through meaningless quantification and comparison.

Read the new literature of deregulation: "What is a life worth?", et cetera. What we read, all too often, is reminiscent of the Renaissance fairy tale about the number of angels that can dance on the point of a needle that supposedly pre-occupied medieval philosophy.

What we do not read is a rich literature that was ancient by the time Aristotle noted that "it is the mark of an educated man to look for precision in each class of things just so far as the nature of the subject admits . . ." (28).

In administrative hearings, briefs submitted in litigation and in nearly any Washington-focused forum the latter-day sophist can be found taking advantage of the utilitarian, albeit superficial utilitarian, poltergeist that has dominated governmental thinking for the past quarter century.

What are our alternatives?

Bentham's felicific calculus (cost-benefit analysis) even with Mill's qualification (the pareto consideration) has little utility in environmental decision-making, because every environmental decision affects someone or some group whose rights and expectations are threatened. Fortunately, there is a moral reality which operates in our society, an historical reality.

In any viable society, the first principle of any ethical system must be the biblical (not necessarily biblically justified) injunction (29) to choose life and its preservation as the means by which to choose right and wrong. This is the basic principle from which all others emanate, including those moral dicta called rights, without which no human society has, could or should survive. Those who recognize the primacy of that principle represent a wide spectrum: witness Spinoza's liberty to preserve man's own existence, Jefferson's location of natural rights in the need for existence, and Freud's identification of the true life instincts with the conservative sexual instinct to preserve life itself.

Thus, a citizen's right to assure that his government attempts to ban the unnecessary proliferation of carcinogens in food (for example) derives from his need for this protection. This and all rights arise from the need to preserve life. This is the historic basis of the Delaney and other regulatory devices, not risk-benefit analysis in the parlor game of "acceptable risk." The fact that we often do not choose life is not an argument for the acceptance of risk. It is, instead, an argument for asking how to reduce risk.

One possible answer is in a concept of necessary risk, based on discoverable historical reality, that is, the need to choose life utilizing not the form of precision identified with mere numbers but the substance of precision through the development of analytic tools consistent with the dialectics of democracy.

To merely suggest this on issues of the environment of the workplace and community is to elicit charges of "Congressional interference" and "emotional publicity." But these come from those who don't understand or choose not to accept the process by which decisions have to be made in a democracy.

Can such a principle become an axiom in a science of health decision? A single calculus of objective and subjective values may not be possible, but a series of calculi utilized dialectically is worthy of exploration if we can discipline ourselves to understand the limitations of an exercise in the mathematics of chance as part of the process of making decisions about who shall live and who shall die.

In this exploration, "we must believe in science, i.e., in determinism; we must believe in a complete and necessary relation between things, among the phenomena proper to living beings as well as in all

others; but at the same time we must be thoroughly convinced that we know this relation only in a more or less approximate way, and that the theories we hold are far from embodying changeless truths" (30).

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